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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/726,960 | 12/03/2003 | James P. Beckham | FMED-26,553 | 4367 |
| 25883 | 7590 | 04/07/2005 | EXAMINER | |
| HOWISON & ARNOTT, L.L.P. | | | THOMPSON, MICHAEL M | |
| P.O. BOX 741715 | | | ART UNIT | |
| DALLAS, TX 75374-1715 | | | PAPER NUMBER | |
| | | | 3763 | |

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|---------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/726,960 | Applicant(s) BECKHAM, JAMES P. | |
| | Examiner Michael M. Thompson | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

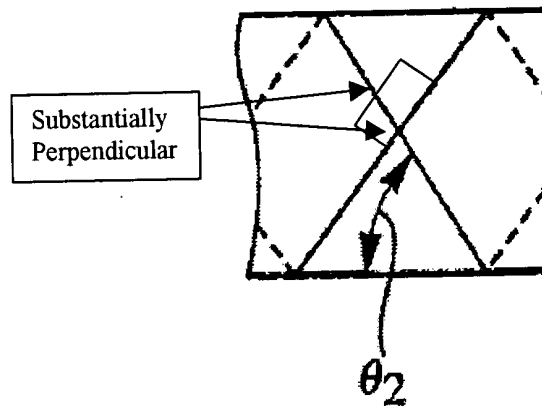
1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruiz (5,868,779) in view of Jorgensen. Ruiz teaches all of the limitations of the claims such as the teaching of PET as non-compliant material suitable for use except for multiple fiber/polymeric outer walls. Jorgensen teaches multiple fiber/polymeric outer walls that form an angle to one other for providing a lower compliance composite balloon device. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the reinforced portion of Ruiz with the reinforced portion of Jorgensen to increase the number of outer fiber/polymeric walls as taught by Jorgensen and for the purpose of lowering compliance since it is well known that the more layers of non-compliant outer walls or mesh that are added serves to reduce compliance of the balloon structure. Furthermore, the Examiner maintains that the method of Jorgensen teaching a layering of outer walls/mesh is analogous to exchanging mesh of different compliance thereby providing additional motivation for their use in the medical art of balloon catheters and the selection of any of these known equivalents to create a reinforced medical device would be within the level of ordinary skill in the art at the time of invention. Furthermore, with respect to Applicant's fiber layer materials it is the Examiner's position that

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Jorgenson teaches polyethylene that meets Applicant's description of inelastic fibers. As shown below it is also the Examiner's position that the fiber layers are "substantially" at a right angle and they are "about" at an angle of 10 degrees.



In addressing the first fibers being equal in length to the long axis of the balloon, the Examiner submits that even though the fibers are helically wound, they are substantially the length of the long axis in that they do not appear to extend past the ends of the balloon section and run substantially the longitudinal length albeit in a helical fashion.

Furthermore, it is the Examiner's position that at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have provided fibers having a thickness of about 0.0005 inch and a second fiber layer wind density of 50 wraps per inch because Applicant has not disclosed that having fiber a thickness of about 0.0005 inch and a second fiber layer wind density of 50 wraps per inch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a fiber thickness of 0.0010 or a second fiber layer wind density of 60 or 40 wraps per inch because

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both the fiber thickness and wind density perform the same function of providing similar non-compliant characteristics of preventing over inflation and elastic characteristic phenomenon and would have functioned equally well. Therefore, it would have been an obvious matter of design choice to modify Ruiz in view of Jorgensen to obtain the invention as specified.

Response to Arguments

Applicant's arguments filed 12/29/2004 have been fully considered but they are not persuasive. Applicant asserts that the prior art of record has failed to teach the interior surface of the non-compliant medical balloon remains substantially unchanged when the balloon changes from a deflated to inflated state. As stated previously, it is the Examiner's position that the prior art teaches a non-compliant balloon device with a interior surface that remains *substantially* unchanged when inflated and deflated due to the non-compliant structure affixed to the balloon. Applicant has not claimed a non-compliant material as the balloon material. Applicant has generally stated a non-compliant medical balloon. It is submitted that in total the prior art balloons are non-compliant. More importantly, the prior art references teach the fiber layers required by Applicant since it appears that Applicant appears to claim a balloon device comprising, two fiber layers and a binding layer. In applying the prior art the Examiner may only rely on the inelastic fiber outer layers to satisfy the limitations of Applicant's claims. If in fact Examiner were to rely upon the entire teaching of the prior art to include the elastic portions, it is the Examiner's position that as taught by Jorgenson the inelastic fibers are affixed to the elastomeric material. In a balloon construction where the inelastic fibers are affixed to the elastomeric balloon material it is submitted that the interior surface area of the elastomeric balloon material is substantially unchanged when inflated and deflated. The mere fact that the

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balloon is secured to the inelastic mesh fibers effectively limits the change of interior surface area of the elastomeric material to exhibit an inelastic behavior when responding to inflation or deflation.


Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (571) 272-4968. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Nick Lucchesi, can be reached on (571) 272-4977. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner


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MT

March 22, 2005